Remarks

Claims 1-48 are pending. Claims 1-26 and 43-48 are withdrawn. Claims 27-42 are rejected.

Rejections under 35 U.S.C. 112, second paragraph

Claims 33-35 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. The Examiner asserts that "substantially free" from an active agent in the specification lacks a standard for measuring the degree intended.

Claims 33 and 35 have been amended, such that these claims only encompass embodiments where barrier layer is free of active agents. (Alternate embodiments on page 32, line 4-7 provide for barrier layers that include compounds which can be added to the barrier layer, or disposed on top of the barrier layer).

With respect to claim 34, which recites that the barrier layer is capable of **substantially preventing diffusion** of the active agent from the coating **prior to the act of directing the beam of charged particles.** The Specification clearly explains that barrier layer 64 can include a semicrystalline polymer having a crystalline zone 66 and an amorphous zone 68. Crystalline zone 66 can be substantially impermeable for an active agent, whereas amorphous zone 68 can be partially permeable to the active agent (page 15, line 2 to page 16, line 3).

Rejections under 35 U.S.C. 103

Claims 27-33 and 35-37 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,837,313 to Ding et al. ("Ding") in view of U.S. Patent No. 6,764,709 to Flanagan ("Flanagan").

Claim 27 defines a method of manufacturing a drug delivery implantable medical

device. The method includes directing a beam of charged particles to the dry polymeric coating to modify the release rate of the active agent from the coating. **The beam of charged particles has a current density from about 0.001 $\mu A/cm^2$ to about 1 $\mu A/cm^2$. The act of directing a beam of charged particles to the dry polymeric coating causes the coating to have an increased release rate of the active agent from the coating**. As described in the specification, the beam of charged particles in the recited range of current density allows the claimed method to increase the release rate of the active agent from the coating, and the claimed method achieves this goal without producing a temperature that significantly degrades the active agent disposed in the coating or adversely affects the polymer in the coating, which is an important technological advancement over prior art.

Ding uses a plasma treatment for sterilizing the coated stent, which is a common procedure in the art. Ding does not describe or teach a method for modifying the release rate of a drug from a coating. Contrary to the Examiner's assertion, the argon plasma treatment described by Ding does not use a beam of argon plasma. In fact, **Ding describes a plasma treatment process in which a coated stent is placed in a reactor chamber and then an argon plasma is subsequently admitted into the chamber**. It is clear to an ordinary skill in the art that the argon plasma in **Ding would not be in the form a beam, but rather, a diffused flowing low pressure argon plasma environment**. For example, Ding describes the argon plasma as having a power range from 200 to 400 watts and a flow rate of 150-650 standard ml per minute, which is equivalent to about 100-450 mTorr, a very low pressure. Applicants respectfully fail to see how Ding led the Examiner to conclude that it described a beam of charged particles rather than an argon

plasma environment. For argument purposes, even if the Examiner's assertion were true that Ding describes a beam of charged particles, Ding still fails to provide a beam of charged articles at the recited current density.

The Examiner asserts that there is no non-obviousness in using a beam of charged particles having the recited current density. This assertion lacks a basic understanding of the claimed invention. As mentioned above, the recited act, directing a beam of charged particles to the dry polymeric coating modifies (increases) the release rate of the active agent from the coating. The ability of the beam to modify (increase) the release rate of the bioactive agent certainly relates positively to the current density of the beam of charged particles. The extent of modification of release rate of the bioactive agent is similarly positively related to the current density of the beam of charged particles.

The Examiner cites Flanagan to support the rejections of claims 27-33 and 35-37 over Ding but fails to discuss the relevance of Flanagan. Flanagan describes a method of forming a coating that includes using a beam of UV laser to ablate a portion of the coating to remove a portion of the coating so as to create a step having a height in the coating (col. 8, lines 24-66). **A beam of UV laser is not a beam of charged particles**. Further, this process degrades the portion of coating, the polymer and the bioactive agent, if any, therein, exposed to the UV laser, which is contrary to the method claimed by claim 27 where a beam of charged particles modifies (increases) the release rate of a bioactive agent in the coating but does not degrade the bioactive agent. Flanagan is therefore irrelevant to the method defined by claim 27.

In sum, claim 27 is patentably allowable over Ding in view f Flanagan under 35 U.S.C. §103(a). Claims 28-33 and 35-37 depend from claim 27 and are patentably

allowable over Ding in view of Flanagan under 35 U.S.C. §103(a) for at least the same reasons.

Claims 34 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding as applied to claims 27-33 and 35-37 above, and further in view of WO 03/022323.

The Examiner is respectfully reminded that, effective November 29, 1999, subject matter which was prior art under former 35 U.S.C. §103 via 35 U.S.C. §102(e) is now disqualified as prior art against the claimed invention if that subject matter and the claimed invention, "were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person" (see MPEP Section 706.02(l)(1)). A statement of an attorney of record can be sufficient evidence to establish common ownership (see MPEP Section 706.02(l)(2)). As established by the enclosed Statement of Common Ownership, at the time the invention of the current application was made, the inventions of the current application and WO 03/022323 were owned by, or subject to an obligation of assignment to, Advanced Cardiovascular Systems, Inc., a California corporation. Since the Applicant has established common ownership, WO 03/022323 is disqualified as prior art under 35 U.S.C. §103(a) and should be removed as a basis for rejection under 35 U.S.C. §103(a).

Claim 38 is rejected under 35 U.S.C. 103(a) as being obvious over Ding as applied to claims 27-33 and 35-37, and in further view of EP 0970711 ("EP 711").

Claim 38 depends from claim 27, which directing a beam of charged particles **having a current density from about 0.001 $\mu A/cm^2$ to about 1 $\mu A/cm^2$** to the dry polymeric coating to modify the release rate of the active agent from the coating. The act of directing a beam of charged particles to the dry polymeric coating causes the coating

to have an increased release rate of the active agent from the coating. As discussed above, Ding fails to describe or teach this important feature of the method of any claims of the instant application. EP 711 describes a method of coating stents but does not describe or teach this element Therefore, Ding and EP 711, individually or combined, does not teach or suggest each and every element of claim 38. Accordingly, claim 38 is patentably allowable over Ding in view of EP 711 under 35 U.S.C. 103(a).

Claims 39-41 were rejected under 35 USC 103(a) as being obvious over Ding and in further view of U.S. Patent No. 6,120,847 to Yang et al. ("Yang").

Claims 39-41 depend from claim 27, which directing a beam of charged particles **having a current density from about 0.001 μA/cm^2 to about 1 μA/cm^2** to the dry polymeric coating to modify the release rate of the active agent from the coating, an important feature that Ding fails to describe or teach. Yang describes a method of eliminating polymeric fibers, polymeric particles or polymeric surface aberrations or imperfections from a polymeric coating on a medical device. The method includes contacting a polymeric coating with the above surface aberrations or imperfections with a vaporized solvent. Yang does not describe or teach directing a beam of charged particles **having a current density from about 0.001 μA/cm^2 to about 1 μA/cm^2** to the dry polymeric coating to modify the release rate of the active agent from the coating. Therefore, Ding and Yang, individually or combined, does not teach or suggest each and every element of any of claims 39-41. Accordingly, claims 39-41 are patentably allowable over Ding in view of Yang under 35 U.S.C. 103(a).

The undersigned authorizes the examiner to charge any fees that may be required or credit of any overpayment to be made to Deposit Account No. 07-1850.

CONCLUSIONS

Withdrawal of the rejection and allowance of the claims are respectfully requested. **If the Examiner has any suggestions or amendments to the claims to place the claims in condition for allowance, applicant would prefer a telephone call to the undersigned attorney for approval of an Examiner's amendment.** If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 393-9885.

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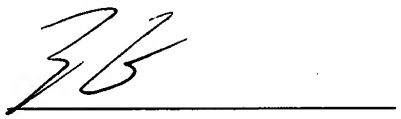
Respectfully submitted,



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